Usefulness of topical lidocaine during esophagogastroduodenoscopy under sedation: A randomized, double-blind clinical trial

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Background: Introduction: The number of endoscopic procedures of the digestive tract has increased considerably worldwide, some of which generate adverse effects that directly influence patient satisfaction; therefore, over time, various modalities have been modified to improve patient comfort before, during, and after the procedure.
Primary objective of the study: To determine and compare patient, anesthesiologist, and endoscopist satisfaction using subjective assessment scales among patients who received topical pharyngeal lidocaine and those who received a placebo.
Materials and methods: A randomized, double-blind clinical trial was conducted with patients referred for endoscopy. A total of 80 patients were studied, divided into two groups of 40 patients, with one group receiving topical anesthesia and the other a placebo. A strategy based on the nature and distribution of the variables was used, with $p < 0.05$ considered statistically significant, following the per-protocol analysis using R 4.2.2.
Results: Both groups were compared, with no significant difference found in propofol doses. Regarding patient and endoscopist satisfaction, there was no significant difference; however, in anesthesiologist satisfaction, there was a significant difference, with a tendency toward greater satisfaction in the group that received topical anesthetic. Regarding complications, there was no difference between the two groups except for a significant increase in the cough reflex during the procedure in the placebo group.
Conclusions: It can be concluded that the application of pharyngeal anesthetic does not provide a clear benefit when endoscopy is performed with intravenous sedation. However, the lower incidence of coughing and the satisfaction reported by the anesthesiologist suggest that this should be evaluated on a case-by-case basis by the anesthesiologist. Therefore, this study does not support the routine use of this medication.

Keywords: Lidocaine, esophagogastroduodenoscopy.

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The number of endoscopic procedures of the digestive tract has increased considerably worldwide, leading to adverse effects that directly influence patient satisfaction; consequently, over time, various approaches have been modified to improve patient comfort before, during, and after the procedure. 1, 2.

Upper endoscopy and colonoscopy can be performed without sedatives; however, most patients report greater comfort when the procedure is performed under the influence of a sedative. 3

Given the above, it has been observed that sedation has made endoscopies better tolerated and, in turn, reduced adverse effects such as coughing, odynophagia, the gag reflex, or even anxiety during the procedure. A review of the literature revealed that in previous years, other medications such as benzodiazepines combined with opioids were the most commonly used sedatives during endoscopies; however, over time, propofol has progressively replaced them as an ultra-short-acting agent. Due to its rapid onset, it has displaced other medications, favoring a brief recovery and improving patient satisfaction without a significant increase in adverse effects. 4-7 Despite its advantages, propofol has a narrow therapeutic window and lacks an antidote, which could pose a risk of excessive sedation if doses are not properly adjusted. 8-9

Some reviewed studies suggest that the use of topical anesthesia could improve patient tolerance during endoscopies without sedation, facilitating their performance. 10-11 .

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Table 1. Baseline characteristics of patients by study group

Variable	Lidocaine (n=40)	Placebo (n=40)	p
Age (years)	56.6 ± 12.3	50.2 ± 15.5	0.045
Weight (kg)	78.4 ± 13.9	81.5 ± 23.4	0.468
Height (cm)	163.1 ± 11.2	165.7 ± 10.1	0.274
BMI (kg/m²)	29.4 ± 5.6	29.6 ± 7.7	0.87
Male (%)	47.5	45	1
ASA III (%)	32.5	20	0.31
Previous endoscopy (%)	37.5	25	0.335
Substance abuse (%)	27.5	25	1

In some procedures performed with sedation, studies suggest that its use could improve patient comfort, but the available evidence regarding its effect when combined with topical anesthesia remains very limited. 12-13

"A clinical study conducted in Spain (De la Morena López, 2011) evaluated this same intervention, finding no differences in the dose of propofol or in the incidence of adverse effects." 14

Given the objective of this study and the lack of consensus regarding its purpose, there is a need to evaluate whether topical pharyngeal anesthesia actually provides any benefit when the patient is already scheduled to receive intravenous sedation with propofol. In the daily clinical practice of this hospital, we have observed symptoms associated with the application of aerosolized lidocaine; however, no adverse effects have been described in the literature, providing us with another point to investigate regarding whether it may cause unwanted effects, such as coughing or discomfort, which could interfere with patient cooperation and complicate the endoscopic procedure.

Therefore, it is pertinent to conduct a comparative analysis of patient, endoscopist, and anesthesiologist satisfaction, as well as the incidence of adverse effects, in patients receiving topical anesthesia versus placebo prior to a diagnostic upper endoscopy under intravenous sedation. This information could help optimize resources, improve the patient experience, and standardize management in endoscopy services.

The primary objective of this study was to determine and compare patient, anesthesiologist, and endoscopist satisfaction using subjective rating scales among patients who received topical pharyngeal lidocaine and those who received a placebo.

Methods

This study was conducted in the Gastrointestinal Endoscopy Unit of a tertiary care hospital between March 1 and August 30, 2025. During this period, 80 patients who met the selection criteria were recruited and randomly assigned to two groups of 40 participants using a computerized allocation method. The sample size was calculated based on a 95% confidence level and a 5% margin of error.

Study Design

This is a randomized, double-blind, controlled clinical trial. Participants were adults over 18 years of age with an indication for non-urgent diagnostic esophagogastroduodenoscopy and an ASA classification of I–III. All participants signed informed consent forms for both the procedure and their inclusion in the study.

Interventions

Group assignment remained blinded to both the endoscopist and the anesthesiologist.

Lidocaine group: A total of 50 mg of topical pharyngeal anesthesia (10% lidocaine) was administered.

Table 2. Procedure parameters and propofol doses by study group

Variable	Lidocaine (n=40)	Placebo (n=40)	p
Total scan time (sec)	812.7 ± 261.3	890.9 ± 519.9	0.399
Partial scan time (sec)	509.1 ± 150.6	646.0 ± 481.7	0.093
Total propofol dose (mg)	175.7 ± 123.5	203.6 ± 188.8	0.437
Partial propofol dose (mg)	85.3 ± 102.8	75.2 ± 144.6	0.719
Mean BIS	70.2 ± 4.0	69.8 ± 5.5	0.729

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Table 3. Satisfaction scores by study group

Variable	Lidocaine (n=40)	Placebo (n=40)	p
Anesthesiologist satisfaction	2.6 ± 0.8	2.1 ± 1.1	0.016
Endoscopist satisfaction	2.8 ± 0.6	2.5 ± 0.8	0.179
Patient satisfaction	2.9 ± 0.5	2.6 ± 0.8	0.063

Placebo group: Received the same spray application, but without the active ingredient.
Both treatments were administered three minutes before inserting the endoscope. The application was performed by trained personnel who were not part of the endoscopy team to preserve the double-blind nature of the study.

Sedation

The protocol for administering propofol sedation consisted of starting with 0.5 mg/kg, followed by bolus doses of 10–20 mg, the latter depending on the patient's clinical response as assessed by the BIS.

Supplemental oxygen was provided via nasal prongs at 4 liters per minute, along with continuous monitoring using pulse oximetry, noninvasive blood pressure, and electrocardiography. The level of sedation was assessed using the Bispectral Index (BIS), targeting values between 70 and 80.

Evaluated variables

Demographic data (age, sex, weight, height, BMI), relevant medical history, ASA classification, indication for the procedure, and airway data were recorded. Total and partial propofol doses, study duration, mean BIS value, completeness of the examination, and the presence of adverse effects were also documented, such as:
Hypoxemia ($SatO_2$ < 90% or a decrease >4%)
Bradycardia
Arterial hypotension
Bronchial aspiration
Allergic reactions
Cough reflex

The satisfaction of the anesthesiologist, endoscopist, and patient was rated using a four-point ordinal scale: very satisfied, satisfied, neutral, and dissatisfied.

Table 4. Overall and specific complications by study group

Event	Lidocaine (%)	Placebo (%)	p
Complications (any type)	15	25	0.402
Desaturation	12.5	7.5	0.712
Hypotension	0	0	1
Bradycardia	0	0	1
Aspiration	0	0	1
Bronchospasm	0	12.5	0.055
Cough	7.5	27.5	0.037
Odynophagia	2.5	7.5	0.615

Results

This study included a total of 80 patients divided into two groups of 40 patients, with one group receiving topical pharyngeal lidocaine and the other receiving only a placebo. Baseline characteristics were compared between the two groups, and no statistically significant differences were found between them in terms of weight, height, body mass index, gender, ASA status, history of prior endoscopy, or substance abuse. The only difference observed was in age, with the lidocaine group being slightly older (56.6 ± 12.3 vs. 50.2 ± 15.5 years, p = 0.045) (Table 1).

Regarding propofol dosage parameters during the procedure, no significant difference was observed between the two groups. The total examination time in seconds was 812.7 ± 261.3 in the topical anesthesia group and 890.9 ± 519.9 in the placebo group, yielding a p-value of 0.399, and regarding the total propofol dose in milligrams, it was 175.7 ± 123.5 in the topical anesthetic group and 203.6 ± 188.8 in the placebo group, with no significant difference between the doses of the two groups. The mean BIS scores for both groups were similar (70.2 ± 4.0 vs. 69.8 ± 5.5, p = 0.729) (Table 2).

Regarding the primary outcome of this study—patient satisfaction—there was no statistically significant difference (2.9 ± 0.5 vs 2.6 ± 0.8, p=0.063), nor was there a significant difference in endoscopist satisfaction (2.8 ± 0.6 vs 2.5 ± 0.8, p=0.179). However, regarding anesthesiologist satisfaction, a significantly greater difference was observed in the group that received lidocaine (2.6 ± 0.8 vs. 2.1 ± 1.1 points, p = 0.016) (Table 3).

Some adverse effects and complications were reported during the procedure, with a similar overall incidence between both groups: a total of

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Table 5. Indications for esophagogastroduodenoscopy in the total sample

Indication	n	%
Dyspepsia	32	40
Reflux disease	14	17.5
Gastritis management	3	3.8
Barrett's control	3	3.8
Dysphagia	6	7.5
Assessment of portal hypertension	14	17.5
Therapeutics	1	1.3
Anemia	6	7.5
Celiac disease screening	1	1.3

15 in the topical anesthetic group and 25 in the placebo group, with no significant difference (p=0.402). No events of hypotension, bradycardia, or aspiration were recorded. Coughing during the procedure was the most common adverse effect, occurring in 27.5% of the lidocaine group vs. 7.5% of the placebo group, a statistically significant difference favoring the group that did not receive the medication (p=0.037); however, this did not affect patient satisfaction but did affect the anesthesiologist's satisfaction. Bronchospasm was another adverse effect observed in the study, occurring exclusively in the placebo group with no significant difference, but a borderline result (12.5% vs. 0%, p=0.055) (Table 4).

The most common indication for upper endoscopy among patients meeting the inclusion criteria for this study was dyspepsia (40%, 32 patients), followed by reflux disease and evaluation of portal hypertension (17.5%(14 patients each), and less frequently dysphagia and anemia at 7.5%; less than 5% of patients had gastritis, Barrett's esophagus, celiac disease, or were undergoing some form of therapy (Table 5).

Discussion

This study included a total of 80 patients divided into two groups of 40 patients, with one group receiving topical pharyngeal lidocaine and the other receiving only a placebo. Baseline characteristics were compared between the two groups, and no statistically significant differences were found between them in terms of weight, height, body mass index, gender, ASA status, history of prior endoscopy, or substance abuse. The only difference observed was in age, with the lidocaine group being slightly older (56.6 ± 12.3 vs. 50.2 ± 15.5 years, p = 0.045) (Table 1).

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Regarding the primary outcome of this study—patient satisfaction—there was no statistically significant difference (2.9 ± 0.5 vs 2.6 ± 0.8, p=0.063), nor was there a significant difference in endoscopist satisfaction (2.8 ± 0.6 vs 2.5 ± 0.8, p=0.179). However, regarding anesthesiologist satisfaction, a significantly greater difference was observed in the group that received lidocaine (2.6 ± 0.8 vs. 2.1 ± 1.1 points, p = 0.016) (Table 3).

Some adverse effects and complications were reported during the procedure, with a similar overall incidence between both groups: a total of 15 in the topical anesthetic group and 25 in the placebo group, with no significant difference (p=0.402). No events of hypotension, bradycardia, or aspiration were recorded. Coughing during the procedure was the most common adverse effect, occurring in 27.5% of the lidocaine group vs. 7.5% of the placebo group, a statistically significant difference favoring the group that did not receive the medication (p=0.037); however, this did not affect patient satisfaction but did affect the anesthesiologist's satisfaction. Bronchospasm was another adverse effect observed in the study, occurring exclusively in the placebo group with no significant difference, but a borderline result (12.5% vs. 0%, p=0.055) (Table 4).

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anemia at 7.5%; less than 5% of patients had gastritis, Barrett's esophagus, celiac disease, or were undergoing some form of therapy (Table 5).

Conclusion

In conclusion, this study found that patients undergoing endoscopies under intravenous sedation and topical anesthesia did not show statistically significant differences compared to the placebo group regarding the study's primary objective. Furthermore, the overall incidence of complications was similar between both groups, so no adverse effects were identified that would justify a clear clinical advantage of topical anesthesia.

It was also found that there is a higher risk of a cough reflex in patients who did not receive topical lidocaine, which was statistically significant but had no impact on patient satisfaction. Regarding anesthesiologist satisfaction, there was a more favorable perception, with greater ease in achieving and maintaining the level of sedation in patients who received the local anesthetic.

Based on the above, it can be concluded that there is no clear benefit when endoscopy is performed with intravenous sedation. However, given the lower incidence of coughing and the satisfaction reported by the anesthesiologist, this should be evaluated on a case-by-case basis by the anesthesiologist. Therefore, this study does not support the routine use of this medication.

Conflicts of interests

The authors declare that there are no financial, personal, or institutional conflicts of interest that could have influenced the work reported in this manuscript.

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